IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

HOSPIRA, INC.

Plaintiff,

v.

SYLVIA MATHEWS BURWELL, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

DR. MARGARET HAMBURG, COMMISSIONER U.S. FOOD AND DRUG ADMINISTRATION,

Defendants,

PAR STERILE PRODUCTS, LLC,

Intervenor- Defendant.

MYLAN INSTITUTIONAL LLC,

Intervenor- Defendant.

Case No. 8:14-cv-02662-GJH

INTERVENOR-DEFENDANT PAR STERILE PRODUCTS, LLC's
MOTION FOR RECONSIDERATION

Intervenor-Defendant Par Sterile Products, LLC, ("Par Sterile"), by and through its undersigned attorneys, hereby request that this Court reconsider and modify its Memorandum Opinion, filed August 19, 2014, (ECF 19).

Par Sterile will rely upon the authorities and exhibits in the attached Memorandum.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21st day of August, 2014, a copy of the foregoing Intervenor-Defendant Par Sterile Products LLC's Motion for Reconsideration was sent by ECF to All Counsel of Record.

/s/ James P. Ulwick
James P. Ulwick

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

HOSPIRA, INC. *Plaintiff,* v. SYLVIA MATHEWS BURWELL, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DR. MARGARET HAMBURG, COMMISSIONER U.S. FOOD AND DRUG ADMINISTRATION, *Defendants,* PAR STERILE PRODUCTS, LLC, *Intervenor-Defendant,* MYLAN INSTITUTIONAL LLC Intervenor-Defendant.	Case No. 8:14-cv-02662-GJH CONFIDENTIAL **FILED UNDER SEAL**

INTERVENOR-DEFENDANT PAR STERILE PRODUCTS, LLC's
MEMORANDUM IN SUPPORT OF ITS MOTION FOR RECONSIDERATION

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The temporary restraining order ("TRO") (Dkt. No. 20) should be vacated in its entirety. The FDA properly approved Par Sterile Products, LLC's ("Par") generic version of Precedex® (dexmedetomidine hydrochloride, 100 mcg/ml (200 mcg/2 mL) vials) on August 18, 2014, and Hospira, Inc. ("Hospira") filed its motion for a TRO and/or preliminary injunction the next day, on August 19, 2014, seeking to substantially delay competition from lower-priced generic alternatives. (Dkt. No. 2.)[1] As the Court is aware, this proceeding is Hospira's second attempt to delay generic entry: Hospira first modified its use code, and although that effort ultimately failed to block generic entry, Hospira obtained an additional eight months delay of generic entry for its effort. Hospira now seeks a TRO to further stall Par's sale of its product.

Par is in the same position as co-defendant Mylan Institutional LLC ("Mylan"): Both Par and Mylan submitted Abbreviated New Drug Applications ("ANDAs") seeking approval of a generic equivalent of Precedex. Both Par and Mylan submitted a Section viii statement for Orange Book listed U.S. Patent No. 6,716,867 ("the '867 patent"), "carving out" the original use identified by Hospira to the FDA. By submitting Section viii statements, Par and Mylan each told the FDA they did not seek to market their respective ANDA products for the use identified in Hospira's Use Code, "Intensive Care Unit Sedation."

Because Par and Mylan share the same position with respect to Hospira, Par hereby relies upon, and incorporates by reference, the arguments made by Mylan in its motion for reconsideration. As described by Mylan, Hospira failed to inform the Court that it must post a

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[1] Hospira filed in TRO in conjunction with a Two Count Complaint against the United States Food and Drug Administration, ("FDA"), Dr. Margaret Hamburg, Commissioner of the FDA, and Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services.

mandatory bond in order to receive a temporary restraining order, and that the failure to require a bond is reversible error in the Fourth Circuit.

BACKGROUND

On February 2, 2012, Par submitted its ANDA seeking FDA approval to market and sell dexmedetomidine hydrochloride injection, 100 mcg (base)/mL, packaged in 200 mcg (base)/ 2 mL single-dose vials ("Par's product"), *i.e.*, Par's generic version of Plaintiff Hospira Inc.'s Precedex® pharmaceutical product. (Ahmend Decl., Dkt. No. 29-2, at ¶ 8.) The ANDA was submitted by JHP Pharmaceuticals, LLC, which which was subsequently acquired and later changed its name to Par Sterile Products, LLC on February 26, 2014.

In 2012, Hospira listed two Orange Book patents for its Precedex product, U.S. Patent Nos. 4,910,214 ("the '214 patent") and the '867 patent. Par certified under Paragraph III that it would not market its product until the expiration of the '214 patent, which expired on January 15, 2014. Par reasonably expected to obtain FDA approval of its product on January 15, 2014, the day of the expiration of the '214 patent. (Pera Decl. at ¶ 4.)[2]

Par took the '867 patent out of play by submitting a Section viii statement. Originally, Hospira told the FDA that its '867 patent was directed to "intensive care unit sedation." Par had no interest in this use, and carved the use out of its drug label, rendering the '867 patent moot for the purpose of Par's FDA approval: Par's product would not be marketed for "intensive care unit sedation."

Days before Par's anticipated approval by the FDA, on January 6, 2014, Hospira modified its use code for the '867 patent to read "intensive care unit sedation, including sedation

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[2] "Pera Decl." refers to the Declaration of Tony Pera in Support of Par Sterile Products, LLC's Motion for Reconsideration, and "Staines Decl." refers to the Affidavit of John C. Staines, Jr.

of non-intubated patients prior to and/or during surgical and other procedures." The manipulation of the use codes was designed to befuddle the FDA, cause the FDA to reconsider FDA approval based on Par and Mylan's Section viii statements, and delay generic competition regardless of its merits. It worked. Even though Hospira's use code manipulation had no basis in law—and therefore is an expressly anticompetitive manipulation of ministerial FDA procedures—on January 15, 2014, the FDA sent a letter to all stakeholders soliciting comments on whether FDA should still approve any ANDAs containing Section viii statements. Hospira's shenanigans effectively stopped the FDA approval process and prevented competition while the FDA reviewed the issue.[3]

Seven months later, on August 18, 2014, the FDA finally approved Par's ANDA No. 203972. (Ahmed Decl., Dkt. No. 29-2, at ¶ 9.) Par began selling its product the next day, on August 19, 2014. (Pera Decl. at ¶ 7.) That same day, Hospira filed its complaint seeking declaratory and injunctive relief against the FDA, alleging that the FDA's decision injured Hospira, and sought a TRO with unprecedented remedies, including requesting an order that the FDA recall all generic products. (Dkt. No. 2.) Blindsided by Hospira, and without the benefit of all the relevant facts, the Court granted the TRO. (Dkt. No. 19.) As soon as Par became aware of the TRO on August 19, 2014, Par halted all sales. (Pera Decl. at ¶ 8.)

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[3] Furthermore, in a nod to the deal that Hospira struck with Sandoz, the current first-to-file PIV certification-containing ANDA holder, Hospira is further seeking to push Par and Mylan out of their section viii statements, forcing them to certify paragraph IV. This would have the effect of blocking their ability to provide a lower-cost generic alternative until the middle of 2015, at which point Sandoz would have been able to exclusively market their generic product at prices that would otherwise not be so elevated. The court should also be aware that the '867 patent was invalidated in the U.S. District Court for the District of New Jersey pursuant to litigation between Hospira and Sandoz. As part of the settlement between those parties, the invalidated patent was the subject of a vacatur motion, after entry of which Hospira sought to assert it against generics.

On August 20, 2014, Par filed an Unopposed Motion to Intervene as a defendant pursuant to Fed. R. Civ. P. 24 (Dkt. No. 29), and the Court granted it. (Dkt. No. 31.) That day, the FDA sent Par a letter notifying Par that based on the Court's TRO, the FDA's decision related to the FDA approval of Par's product "has been stayed, and the FDA will not take additional action based on that decision while the temporary restraining order remains in effect." (Pera Decl. at ¶ 9, Ex. 4.) Because Hospira never named Par as a defendant, Par had no opportunity to be heard at the TRO hearing held on August 19, 2014.

Par files this Motion for Reconsideration of the TRO to point out facts and legal authorities in support of its position that the Order Granting the Motion for Temporary Restraining Order should be rescinded. Hospira's demand for a TRO is both factually and legally wrong.

LEGAL STANDARDS

Federal Rule 54(b) governs motions for reconsideration of interlocutory orders, which states in relevant part "any order . . . may be revised at any time before the entry of a judgment adjudicating all claims and all parties' rights and liabilities." Fed. R. Civ. P. 54(b). "A court's discretion to review an interlocutory order is not subject to the strict standards applicable to motions for reconsideration of a final judgment, but is within the plenary power of the court to afford such relief as justice requires." *Cohens v. Md. Dept. of Human Resources,* 933 F. Supp. 2d 735, 742 (D. Md. 2013) (Quarles, J.) (citations and internal quotations omitted). "In considering whether to revise interlocutory decisions, District Courts in this Circuit have looked to whether the movants presented new arguments or evidence, or whether the Court has obviously misapprehended a parties position or the facts or applicable law." *Id.* at 742–43. Resolution of a motion for reconsideration "is committed to the discretion of the district court."

Am. Canoe Ass'n v. Murphy Farms, Inc., 326 F.3d 505, 514–15 (4th Cir. 2003). Here, the arguments and evidenced presented by Par are by definition new, since the Court has not had the opportunity to hear from Par up until this time. Thus, the Court has the plenary power to afford such relief as justice requires. In this case, justice requires reconsideration and modification of the temporary restraining order.

ARGUMENT

I. HOSPIRA IS NOT LIKELY TO SUCCEED ON THE MERITS.

For the reasons set forth in Mylan's motion for reconsideration, Hospira's motion for a TRO and/or preliminary injunction is little more than a delay tactic, one that thwarts lawful competition. After Hospira modified its patent use code on January 6, 2014, the FDA solicited and reviewed comments from all ANDA filers, and spent eight months deliberating as to whether to approve Par's generic product, which dilatory and ministerial tactic successfully prevented lower cost generics from entering the market. The FDA correctly decided to approve Par's ANDA.

As detailed in Mylan's motion for reconsideration, Hospira never informed the Court that Fed. R. Civ. P. 65(c) prohibits a TRO unless "the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 (4th Cir. 1999) (a "district court must fix a bond whenever it grants a preliminary injunction or restraining order.") "This rule is mandatory and unambiguous" and "failure to require a bond upon issuing injunctive relief is reversible error." *Id.* (citations omitted); *see also Pashby v. Delia*, 709 F. 3d 307, 331–32 (4th Cir. 2013). By failing to inform the Court that it must consider the mandatory question of a bond, Hospira procured a temporary restraining order that is not enforceable. The approximate amount for the bond should be $26 million based on the

scenario where Par would be forced to stay off the market for 10 months from now—which is four months through December 2014 when Sandoz launches, and six months after Sandoz's launch, presuming Par is forced to convert to a PIV certification.

II. HOSPIRA WILL NOT SUFFER IRREPARABLE HARM.

Par incorporates by reference the points and authorities asserted by Mylan in demonstrating that Hospira would, at worst, suffer only compensable monetary damages—not irreparable harm—if the Court were to deny the injunction *and* Hospira were to ultimately succeed in reversing the FDA's considered decision reached after months of deliberation and opportunity for public comment. If Hospira is ultimately unsuccessful in overturning the FDA's decision, then Hospira will have suffered no harm.

Par also seeks to bring to the Court's attention the additional perspective provided in the attached affidavit of economist John C. Staines, Jr. Among other important points, Mr. Staines explains that any potential harm to Hospira is particularly calculable here (and thus not irreparable) because Hospira already has agreed to generic entry beginning no later than four months from now on December 26, 2014. (Staines Decl. at ¶¶ 6–7, 11–12.)

As Mr. Staines details, because the issue before this Court is merely whether Hospira can prolong its monopoly profits over that discrete period of four months, there is no basis for finding that any potential harm to Hospira is irreparable as opposed to readily calculable. Mr. Staines proceeds to address additional facts relevant to the harm to Par Sterile and the public if the Court maintains an injunction foreclosing readily available generic alternatives.

III. PAR WOULD BE IRREPARABLY HARMED BY A TRO: THE BALANCE OF EQUITIES STRONGLY DISFAVORS AN INJUNCTION HERE.

Both the delay in FDA approval and any recall of Par's product would irreparably damage Par. Every day of delay hurts Par. Unless the FDA reinstates the approval of Par's

product, Par will suffer significant non-economic harms, including the loss of good will and relationships Par developed with its customers; the loss of business opportunities; and a substantial loss of market share. (Staines Decl. at ¶¶ 7–10.)

A. The Recall of Par's Products Would Be Unprecedented, and Irreparably Harm Par's Reputation in the Industry, in addition to Costing Par Millions of Dollars.

Hospira's request for a recall is unprecedented. Neither the FDA nor any court has ever recalled a drug product for reasons pursuant to a reading of the "use code." The recall of Par's products would financially devastate Par. (Pera Decl. at ¶ 13; Staines Decl. at ¶ 12–13.) As soon as the FDA approved Par's product on August 18, 2014, Par shipped its product. (Pera Decl. at ¶ 13.) On a single day—August 19, 2014—Par sold [redacted] of its product, worth [redacted] in revenue. (*Id.*) If recalled, all of this product would have to be destroyed. (*Id.*)

In the last ten years, the FDA has only recalled two Par products out of hundreds that were manufactured, and in each case, all units were destroyed. (*Id.* at ¶ 14.) Par has no protocol or system in place to sell and deliver a product, recall it, store it, and then resell it to its customers again. (*Id.*) Once the product leaves Par's chain of custody, it cannot be resold for a host of reasons. (*Id.*) First, it is unclear what portion of the sold products can even be recalled because much of Par's products may have already made their way to patients and possibly even used. (*Id.*) Par's customers are drug wholesalers. (*Id.*) Second, Par's product is temperature controlled. Par's label states: "Store between 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature.)." (*Id.*) Because Par cannot know how customers stored the product before shipping it back to Par, Par's later sale of such products would violate FDA regulations. (*Id.*)

Third, Par would likely have to destroy any of Par's product already manufactured due to the impending expiration dates of the product. (*Id.* at ¶ 15.) Although Par's product has a shelf-

life of 24 months, by both contract and industry custom, Par cannot sell any product that does not have at least 12 months of its shelf-life remaining. (*Id.*) Par began manufacturing batches of its product in September 2013, on the expectation that the FDA would approve its ANDA in January 2014. (*Id.*) Within the next few weeks, starting in September 2014, all of those products will have less than one-year of shelf-life remaining and Par will no longer be able to sell them to any of its customers. (*Id.*) And fourth, even if Par could resell recalled products, the cost to do so would be prohibitively expensive and damage Par's reputation in the industry. (*Id.*; Staines Decl. at ¶ 13.)

Even if Par could resell recalled products, Par is not equipped to handle voluntarily recalled products. (Pera Decl. at ¶ 16.) Pursuant to FDA regulations, Par would have to develop a proper and validated way to inspect each of the returned vials, and Par would have to create a validated method for inspection and reshipment of recalled products—which costs time and money. (*Id.*) Furthermore, each shipment of glass vials results in breakage for some percentage of the vials. (*Id.*) Even a hairline fracture in a vial can compromise the drug's sterility—which is catastrophic for a sterile injectable product such as Par's product. (*Id.*) Not only would Par have to pay for the returned shipments from its customers, Par has every reason to expect that customers returning a "recalled" product would be less careful than Par in packing the product for shipment because its customers would presume that Par intended to destroy it anyway. (*Id.*) Even worse, by reneging on existing contracts, Par would have to pay penalties, which in some cases, are more than the value of the product itself. (*Id.*)

Even if Par spends the enormous resources and time to recall its products, there is no reason to believe that wholesalers would buy them. (*Id.* at ¶ 17.) Because drug recalls have only ever occurred due to safety or efficacy reasons, and never for Because drug recalls have only

ever occurred due to safety or efficacy reasons, and never for reasons associated with the "use code," customers are likely to presume that Par is attempting to sell damaged, and even potentially dangerous, goods. (*Id.*; Staines Decl. at ¶ 13.) The mere attempt to sell "recalled" drug products would tarnish Par's reputation in the industry. (Pera Decl. at ¶ 17; Staines Decl. at ¶¶ 12–13.) All drug recalls are published on the FDA website, and again, because the type of recall sought by Hospira in unprecedented, the industry is likely to assume that Par had safety or efficacy problems with its products. (Pera Decl. at ¶ 17.) Therefore, beyond the financial devastation Par would endure from a recall, Par's reputation would be irreparably harmed.

B. Delaying the FDA Approval of Par's Product Harms Par.

The FDA's suspension of approval for Par's product is already hurting Par. (Pera Decl. at ¶ 10.) In just one day, Par had to turn away two customers, [redacted]. (*Id.*) Other customers have already contacted Par out of concern over Hospira's legal proceedings. (*Id.*) Every day Par's approved product is kept off the market costs Par substantial sums of money. (*Id.*; Staines Decl. at ¶ 12.)

Par's window of opportunity to sell its product is fleeting. Hospira and Sandoz admit that pursuant to a settlement between them, Sandoz will enter the market for generic dexmedetomidine in December 2014, fewer than four months from now. (Dkt. No. 2 at 25.) Once Sandoz enters the market, the market converts, and Par will suffer long-term harm associated with the limited opportunity to compete for market share. (Staines Decl. at ¶¶ 12–13.) In the end, Hospira's efforts to undermine the FDCA and force Par and Mylan into the penumbra of Sandoz's exclusivity (from which Hospira and Sandoz would unfairly benefit), would have unjustifiably borne fruit.

As one of the first generic products on the market, Par is entitled to the advantages associated with being among the first entrants in the generic market. Par earned and deserves a

significant first-entrant advantage, including the ability to establish contracts and relationships that persist even after its formal first-entrant advantage fades. (Pera Decl. at ¶ 11.) Other generics, including Akorn and Caraco, are waiting in the wings. (*Id.*, Ex. 5; Staines Decl. at ¶¶ 6, 12.) Each company has tentative FDA approval. If Par's FDA approval is delayed, Par's advantage in being one of the first approved generic products evaporates and there is no recompense available to it for that loss.

By being one of the first generic products, Par would be able to gain a significant customer base, and offers the unique ability to leverage long-term contracts. (Pera Decl. at ¶ 12; (Staines Decl. at ¶ 12.) If FDA's final approval of Par's ANDA continues to be suspended, or ultimately rescinded, Par expects to lose existing contracts with large purchasers and other first-to-market advantages, including the opportunity to supply major customers with other, non-exclusive products. (Pera Decl. at ¶ 12; Staines Decl. at ¶¶ 12–13.) Par's customers will also be harmed because they will be forced to purchase Precedex at Hospira's inflated, monopolistic prices. (Pera Decl. at ¶ 12; Staines Decl. at ¶ 14.)

Another important consideration is the fact that the market for Precedex is shrinking due to Hospira's own conduct. Anticipating the loss of its monopoly for Precedex, Hospira has already started replacing the market for Precedex with a new version of the drug called Precedex Premix, which is a ready-to-use ("RTU") version of Precedex. (Staines Decl. at ¶¶ 5, 9, 11, 15.) Introducing a new version of an older drug is called a "life-cycle" play by the brand name drug pharmaceutical industry, *i.e.*, when a product is about to go generic, introduce a new version of it and stop promotion of the old one. At this very moment, Hospira is attempting to switch its current vial formulation customers to the ready-to-use formulation that Par does not have

approval to sell. (Staines Decl. at ¶¶ 9, 11, 15.) Every day that Par is unable to ship its generic product, the market for Precedex shrinks.

In considering whether the balance of equities favors granting a preliminary injunction, courts consider whether an injunction would "'substantially injure other interested parties.'" *Viropharma, Inc. v. Hamburg, et al.*, 898 F. Supp. 2d 1, 28 (D.D.C. 2012) *citing McGinn, Smith & Co., Inc. v. Fin. Indus. Regulatory Auth.*, 786 F.Supp.2d 139, 144 (D.D.C. 2011) (internal citations omitted); *and see Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24, 129 S.Ct. 365 (2008) (holding that court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.") (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987)).

IV. THE PUBLIC INTEREST WILL NOT BE SERVED BY A TEMPORARY RESTRAINING ORDER.

Because the points and authorities asserted by Mylan on this fourth required element for a temporary restraining order or preliminary injunction are generally applicable to both Defendant-Intervenors, Par hereby adopts and incorporates those points by reference.

Par seeks to emphasize two additional points, however. First, as Hospira admits in its most recent annual report: "In December 2013, Hospira entered into a settlement in its patent litigation over Precedex . . . provid[ing] for a market entry date for Sandoz to sell a generic version of Precedex no later than December 26, 2014." (Hospira, Inc. Annual Report 2013 at 52.) Thus, since last year, Hospira has known for certain that the sun was setting on the monopoly profits from its Precedex vial formulation product, which will be genericized four months from now. (Staines Decl. at ¶ 18.)

The issue before this Court under the fourth TRO element, accordingly, is straightforward: how will the public benefit from Hospira prolonging its monopoly profits for as

long as possible over the next four months? The answer is that there is no measurable public benefit because the higher profits that Hospira would earn due to an injunction correlate inescapably with the higher prices that consumers in the general public would pay for the Precedex vial formulation—in particular consumers who are hospital patients. (*See* Staines Decl. at ¶¶ 14–15.)

Courts weighing the public interest element in this context of being asked to remove existing generic alternatives from the marketplace have readily resolved the question in favor of lower prices for consumers: "The public interest favors denying the preliminary injunction. As both parties note, hundreds of thousands of Americans rely on simvastatin on a daily basis. And until recently, a monopoly has existed in the simvastatin market. But with the entrance of Ivax and Ranbaxy's generic simvastatin, the monopoly that existed has ended. Ivax's generic simvastatin product is now being distributed to end users and Ranbaxy is actively marketing their generic brand. If this Court enters the injunction requested by Sandoz, however, it will effectively take Ivax and Ranbaxy's low-cost generic simvastatin product out of the hands of consumers. Thus, Sandoz's proposed injunction would not only harm hundreds of thousands of patients, it would also go against the clear purpose of the Hatch–Waxman Act, which is to 'get generic drugs into the hands of patients at reasonable prices—fast.'" *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 33 (D.D.C. 2006) (quoting legislative history).

Here, the public likewise has a far greater interest in continued access to the existing, lower-priced generic alternatives than any possible indirect public benefit that might be imagined by delaying the inevitable and prolonging Hospira's monopoly profits for another four months.

The other important consideration relevant to the public interest element is the antitrust implication of awarding Hospira yet another delay measure as the company seeks to run out the clock on its four remaining months of monopoly profits. Once it was clear that Par and Mylan, should they maintain their section viii certifications, would be able to launch immediately, Hospira took the *unprecedented* step of changing the use codes on the product to preclude the generics from marketing.

That maneuver by Hospira ultimately failed to stop the generics altogether—but it did buy Hospira *another eight months* of monopoly profits while the FDA considered, and invited public comment upon, the unprecedented regulatory barrier erected by Hospira. Furthermore, Hospira's changing of the use codes was also the handmaiden to the ultimate goal of forcing Par and Mylan to change their section viii statements to PIV certifications, effectively removing them as competition until Sandoz's 180 day marketing exclusivity had expired.

Respectfully, the Court might consider this question: if Hospira claims irreparable harm from potential lost profits over the next four months, how much did consumers in the general public lose over the eight months of delayed generic entry caused by Hospira's failed use-code maneuver and how much would the general public lose were Par and Mylan to be blocked for an additional 10 months from delay should Hospira effectively reverse the FDA's decision and force the generics into new certifications?

Undeterred, as soon as one barrier fell, Hospira raised its next one: this TRO proceeding seeking an unprecedented order to the FDA to recall generic product absent a public health threat flowing from a safety or efficacy failure. With only four months of monopoly profits remaining, Hospira is well aware that it does *not* have to prevail in overturning the FDA's order to make this

suit worth the candle: every extra day of delayed generic entry brings a tidy sum of extra monopoly profits.

Win or lose against the FDA on the merits, an injunction here means that Hospira wins a little more each day. In that sense, Hospira's maneuvers are entirely rational. But virtually all anticompetitive conduct is rational. It is not irrationality that calls anticompetitive conduct into question. It is the antitrust laws that make such conduct questionable.

The antitrust implications of granting Hospira a second substantial delay of generic entry are further evidence that an injunction here cannot serve the interest of the public.

CONCLUSION

For all of the reasons set forth above, this Court should rescind the Temporary Restraining Order. Hospira's motion for a TRO is just another attempt to stop generic competition, which allows Hospira to sell its Precedex product at inflated prices.

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